

§ 1314.110

(b) If the product is being shipped to a third party, the regulated person must comply with the requirements of paragraph (a) to verify that both the purchaser and the person to whom the product is being shipped live at the addresses provided. If the regulated person cannot verify the identities of both the purchaser and the recipient, the person may not ship the scheduled listed chemical product.

§ 1314.110 Reports for mail-order sales.

(a) Each regulated person required to report under § 1310.03(c) of this chapter must either:

(1) Submit a written report, containing the information set forth in paragraph (b) of this section, on or before the 15th day of each month following the month in which the distributions took place. The report must be submitted under company letterhead, signed by the person authorized to sign on behalf of the regulated seller, to the Import/Export Unit, Drug Enforcement Administration (see the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address); or

(2) Upon request to and approval by the Administration, submit the report in electronic form, either via computer disk or direct electronic data transmission, in such form as the Administration shall direct. Requests to submit reports in electronic form should be submitted to the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(b) Each monthly report must provide the following information for each distribution:

(1) Supplier name and registration number;

(2) Purchaser's name and address;

(3) Name/address shipped to (if different from purchaser's name/address);

(4) Method used to verify the identity of the purchaser and, where applicable, person to whom product is shipped;

(5) Name of the chemical contained in the scheduled listed chemical product and total quantity shipped (*e.g.* pseudoephedrine, 3 grams);

(6) Date of shipment;

(7) Product name;

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(8) Dosage form (*e.g.*, tablet, liquid);

(9) Dosage strength (*e.g.*, 30mg, 60mg, per dose etc.);

(10) Number of dosage units (*e.g.*, 100 doses per package);

(11) Package type (blister pack, etc.);

(12) Number of packages;

(13) Lot number.

[71 FR 56024, Sept. 26, 2006, as amended at 75 FR 10684, Mar. 9, 2010]

§ 1314.115 Distributions not subject to reporting requirements.

(a) The following distributions to nonregulated persons are not subject to the reporting requirements in § 1314.110:

(1) Distributions of sample packages when those packages contain not more than two solid dosage units or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.

(2) Distributions by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as specified in § 1300.02(b)(29) of this chapter, except that this paragraph (a)(2) does not apply to sales of scheduled listed chemical products at retail.

(3) Distributions to a resident of a long term care facility or distributions to a long term care facility for dispensing to or for use by a resident of that facility.

(4) Distributions in accordance with a valid prescription.

(b) The Administrator may revoke any or all of the exemptions listed in paragraph (a) of this section for an individual regulated person if the Administrator finds that drug products distributed by the regulated person are being used in violation of the regulations in this chapter or the Controlled Substances Act.

Subpart D—Order to Show Cause

§ 1314.150 Order To show cause.

(a) If, upon information gathered by the Administration regarding any regulated seller or a distributor required to submit reports under § 1310.03(c) of